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LETTER

Patient-centered outcomes and trials of hydroxyethyl starch

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Meybohm and colleagues [1] propose that hydroxyethyl starch (HES) may be used safely in hypovolemic patients by applying a clinical algorithm and by restricting the dose administered.

The authors question the validity of the results of the two trials that constitute over 60% of current data [2,3] and misleadingly state that in the Crystalloid vs. Hydroxyethyl Starch Trial (CHEST), HES administration did not increase the use of renal replacement therapy by referring to the adjusted analyses that were published in the electronic supplement [2]. The unadjusted analysis was pre-specified as the principal outcome measure and is the appropriate measure to influence clinical practice. The authors also ignore the consistent signal of harm associated with HES, specifically increased mortality and use of renal replacement therapy that is evident despite wide variations in aggregate doses of HES in the three major clinical trials: 70 ml/kg in the Efficacy of Volume Substitution and Insulin Therapy in Severe Sepsis trial [4], 44 ml/kg in the Scandinavian Starch for Severe Sepsis/Septic Shock study [3], and 5 ml/kg in CHEST. Meybohm and colleagues make no comment that adverse effects of HES represent an overall toxic effect caused by increased tissue accumulation that is recognised as a dose-dependent, generic HES effect [5].

The 'presumably correct indication' and the algorithm they propose have not been validated nor are they supported by any credible clinical evidence. Their proposed algorithm and target population must be evaluated in rigorously conducted randomized controlled trials before being considered for adoption into clinical practice. Given the consistent evidence that HES is nephrotoxic and may increase mortality [6], it is doubtful that institutional ethics committees would approve such a trial, or that informed patients would consent to participate.

Abbreviations

CHEST: Crystalloid vs. Hydroxyethyl Starch Trial; HES: Hydroxyethyl starch.

Competing interests

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